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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,820	02/10/2006	Jae-Hong Kim	012679-114	3987
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EXAMINER McCORMICK, MELENIE LEE				
ART UNIT 1655		PAPER NUMBER		
NOTIFICATION DATE 04/28/2009		DELIVERY MODE ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ADIPFDD@bipc.com

### Office Action Summary

**Application No.**

10/551,820

**Applicant(s)**

KIM, JAE-HONG

**Examiner**

MELENIE MCCORMICK

**Art Unit**

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 February 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 17-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 17-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
- Paper No(s)/Mail Date \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09 February 2009 has been entered.

Claims 1 and 17-21 are pending.

Claims 20-21 stand rejected as being drawn to the non-elected invention.

Claims 1 and 17-19 are presented for examination on the merits.

### ***Withdrawn Rejections***

The previous rejection under 35 U.S.C. 102(b) or in the alternative under 35 U.S.C. 103(a) has been withdrawn because claim 3 has been cancelled.

The previous rejection under 35 U.S.C. 103(a) has been withdrawn in light of the amendment to the claims which recite 'due to the accumulation of eosinophiles' and upon further consideration.

***New Rejections***

***Claim Objections***

Claims 17 and 19 are objected to because of the following informalities: the claims recite 'Formula 1', but Formula 1 is not present in the claims. Although the structure of pelargonidin is well known, the claims recite a formula which is not present in the claims. It is suggested that the actual 'Formula 1' be either added to the claims or that the term 'Formula 1' be removed from the claims. Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 17-19 are rejected under 35 U.S.C. 102(b) as anticipated by Nair et al. (WO 01/15553 A1) as evidenced by Kraneveld et al. (1997) and Creticos (2000).

Nair et al. teach a method of treating an inflammatory response in an animal by administering to the animal a composition (fruit extract) which has anti-inflammatory activity (see e.g. claim 19). Nair et al. further teach that the inflammatory response may be asthma (i.e. bronchial asthma) (see e.g. claim 20). Nair et al. also teach that the

composition comprises pelargonidin (see e.g. claim 21). Please note that the term 'black rice extract' is broad enough to read on just one compound extracted from black rice, including as pelargonidin, as claimed. Because Nair et al. disclose that the anti-inflammatory activity of the extract is mediated by pelargonidin (see e.g. page 3, lines 1-14), the pelargonidin present in the extract composition (even if only a small amount), is present in an effective amount. Nair et al. do not explicitly teach asthma is due to the accumulation of eosinophiles, however, as evidenced by Kraneveld et al., the accumulation of eosinophilic leukocytes (eosinophiles) is a prominent feature of inflammatory reactions that occurs in allergic asthma (see e.g. abstract). Therefore, the accumulation of eosinophiles is something that occurs in asthma and treating asthma would be treating asthma involving the accumulation of eosinophiles. In addition, although Nair et al. do not explicitly teach the use of pelargonidin for treating symptoms of asthma, however, as evidenced by Creticos et al., that the key to successful management of the asthmatic disease process is not only to treat the acute symptomology of but more importantly to suppress the underlying inflammatory component, which results in a reduction of bronchial hyperresponsiveness, attenuation of diurnal variability, with improvement in lung function, and a reduction in the chronic symptoms of asthma (see e.g. page S940). Therefore, treating asthma, specifically with an anti-inflammatory agent as taught by Nair et al., results in a reduction in asthma symptoms and is therefore treating symptoms of asthma.

***Response to Arguments***

Although the previous rejections have been withdrawn, the arguments pertinent to the new rejections are discussed below.

Applicants argue that references fail to teach or suggest the claimed invention that is directed to a method for treating bronchial asthma and symptoms of bronchial asthma 'due to the accumulation of eosinophiles in cells, tissues or a body', comprising administering an effective amount of black rice extract to an individual in need thereof. Applicants further argue that bronchial asthma due to the accumulation of eosinophiles is a different process belonging to late phase reaction (LPR) than bronchial asthma due to an immediate-type allergy to various allergens belonging to early phase reactions (EPR) and that the references teach bronchial asthma due to an immediate-type allergy to various allergens. This is not found persuasive. As previously stated, Kraneveld et al. teach that the accumulation of eosinophilic leukocytes (eosinophiles) is a prominent feature of inflammatory reactions that occurs in allergic asthma (see e.g. abstract). Therefore, the accumulation of eosinophiles is something that occurs in allergic asthma and treating allergic asthma would be treating asthma involving the accumulation of eosinophiles. While eosinophiles may accumulate later in an asthmatic attack (i.e. not immediately), Applicants have not provided evidence that an allergic asthmatic reaction does not involve eosinophiles or that there is a different kind of asthma that does not involve the accumulation of eosinophiles. Therefore, in the absence of evidence to the contrary and in light of Kraneveld et al., the treatment of asthma using an antihistamine

rendered obvious by the instantly cited reference is a treatment for asthma caused by an accumulation of eosinophiles.

The rejection is therefore deemed proper and is maintained.

### ***Conclusion***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELENIE MCCORMICK whose telephone number is (571)272-8037. The examiner can normally be reached on M-F 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Patricia Leith/  
Primary Examiner, Art Unit 1655